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TITLE: Do Capacity Coupled Electric Fields Accelerate Tibial Stress Fracture Healing?

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13. ABSTRACT (Maximum 200 Words)

A convenience sample based on availability of tibial stress fracture cases at local Sports Medicine Clinics will be selected over 4 years until forty subjects (20 male, 20 female) have been treated. The study is designed to be able to determine if electric field stimulation accelerates the healing of tibial stress fracture and whether there are gender effects. Only posteromedial mid to distal third and proximal medical tibial condylar stress fractures will be investigated. Four imaging approaches will be used at diagnosis (radiographs, bone scan, MRI and CT). All subjects will be identically treated in a double blind fashion using active or passive electric field stimulator devices (that apply a sinusoidal wave of 3-6 V, 60 KHz, 5-10 mA), to be worn 15-20 hours per day, and other standardized rehabilitation treatments, until healed but not longer than 6 months. Subjects will be considered healed when hopping on the affected limb is no longer painful. Only MRI will be used for follow-up studies. A grading system will be developed for each of the diagnostic methods and compared to the ability of the MRI grading system to predict time to recovery.

14. SUBJECT TERMS
No subject terms provided.

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INTRODUCTION

This double blind placebo-controlled study is designed to determine if electric field stimulation will accelerate the healing of tibial stress fractures. Additionally a stress fracture severity grading system is to be developed for four different diagnostic imaging techniques (plain films, nuclear medicine scans, MRI and CT). The purpose of the imaging study is to determine the most cost effective approach for tibial stress fracture diagnosis and the most effective technique to predict time to healing. Twenty male and twenty female subjects are to be recruited in order to discriminate gender effects. All subjects are treated identically with an active or inactive electric field stimulator device (active devices apply a sinusoidal wave of 3-6 V, 60 KHz, 5-10 mA.) Subjects wear the units for 15-20 hrs/day until healed, with a maximum treatment time of 6 months. Subjects are considered healed when 30 seconds of hopping on the affected limb is nonpainful.

BODY

In the Revised Statement of Work (October 2003) activities that remained to be completed included:

1. Recruit and treat final 13 subjects
2. Begin analysis of healing data
3. Begin analysis of radiological images
4. Prepare final report
5. Present data at ACSM

Ongoing Activities included:

1. Collect data, including: subject consenting, evaluation, consultation and data collection (Food Frequency and Activity History Questionnaires), radiology appointment making, OrthoPak training, subject monitoring
2. Liaison with referring clinicians

Update

A no-cost extension was granted 8/17/04 to extend the performance period from 9/14/04 to 12/15/05. This arrangement accounted for data collection time lost to the process of subcontracting to Griffith University. We expect to complete collection of the final two data sets and initiate data analysis in the coming months.

KEY RESEARCH ACCOMPLISHMENTS

- Data collection on 41 subjects (38 complete data sets) in total has been completed (9 at Stanford University and 32 at Griffith University)

SUBJECT #	SEX	AGE	PRIMARY SPORT	TREATMENT TIME (days)	RECRUITING UNIVERSITY
1	Female	32	Running	18	Stanford University
2	Male	35	Running	19	Stanford University
3	Female	46	Running	23	Stanford University
4	Female	16	Running	25	Stanford University
5	Male	30	Running	14	Stanford University
6	Male	22	Running	14	Stanford University
7	Male	18	Running	21	Stanford University
8	Female	33	Running	18	Stanford University
9	Male	19	Running	6	Stanford University
10	Male	23	Running	23	Griffith University
11	Female	21	Aerobics	2	Griffith University
12	Female	18	Sprinting	25	Griffith University
13	Female	21	Sprinting	18	Griffith University
14	Female	34	Running	37	Griffith University
15	Female	18	Running	12	Griffith University

16	Female	22	Running	Released from study after failure to follow protocol.	Griffith University
17	Male	37	Running	7	Griffith University
18	Male	37	Running	6	Griffith University
19	Male	33	Triathlete	17	Griffith University
20	Male	25	Running	8	Griffith University
21	Male	25	Running	8	Griffith University
22	Female	34	Triathlete	17	Griffith University
23	Female	23	Step aerobics	19	Griffith University
24	Female	32	Running	17	Griffith University
25	Male	21	Boxing/running	15	Griffith University
26	Male	21	Boxing/running	16	Griffith University
27	Male	42	Running	9	Griffith University
28	Male	24	Sprinting	6	Griffith University
29	Female	24	Netball	Stress fractures 29 and 30 were bilateral injuries in the same individual. She was recruited following diagnosis by an orthopaedic surgeon. She was released from the study after 30 days of intervention and rest from pain-provoking activities as a total lack of change in symptoms was not consistent with the progression of normal stress fracture resolution. She was referred for further evaluation to a sports medicine physician who diagnosed a complex regional pain syndrome Type I.	Griffith University
30	Female	24	Netball		Griffith University
31	Female	31	Aerobics	22	Griffith University
33	Female	31	Aerobics	44	Griffith University
33	Male	23	Australian Rules	3	Griffith University
34	Male	23	Australian Rules	14	Griffith University
35	Female	23	Treadmill running	8	Griffith University
36	Female	23	Treadmill running	8	Griffith University
37	Male	24	Australian Rules/ Running	11	Griffith University
38	Female	32	Netball/ gym	60	Griffith University
39	Female	29	Treadmill running	21	Griffith University
40	Female	21	Treadmill running	11	Griffith University
41	Female	21	Treadmill running	11	Griffith University

REPORTABLE OUTCOMES

There are no reportable outcomes to date as subject data remains blinded from investigators until the end of the study.

CONCLUSIONS

There are no reportable conclusions to date.

REFERENCES

NA

APPENDICES

NA